

REMARKS

Claims 1-38 are pending. New claim 38 has been added and is supported by the SEQ ID NO 9 and originally filed claim 13. Accordingly, no new matter has been added.

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Restriction Requirement

In the Office Action the Examiner has required restriction to one of the following groups under 35 U.S.C. §121:

I-VIII. Claims 1-2, 5, 9-15, drawn to a nucleic acid encoding an alternative splicing variant of tumor necrosis factor receptor protein, an expression vector, and a host cell;

IX-XVI. Claims 3-4, 12-15, 31-35, drawn to a splicing variant of a tumor necrosis factor receptor protein;

XVII-XXIV. Claims 6-8, 14-15, drawn to an antibody to a splicing variant of tumor necrosis factor receptor protein;

XXV-XXXVI. Claims 16-17, 18-21, drawn to a method detecting the presence of a nucleic acid encoding a splicing variant of tumor necrosis factor receptor protein in a sample;

XXXVII-XXXXII. Claims 22-24, drawn to a method of identifying candidate compounds capable of binding a splicing variant of tumor necrosis factor receptor protein;

XXXXIII-XXXXVII. Claim 25, drawn to an agonist of a splicing variant of tumor necrosis factor receptor protein;

XXXXIX-LVI. Claim 26, drawn to an antagonist of a splicing variant of tumor necrosis factor receptor protein; and

LVII-LXIV. Claims 27-30, 36-37, drawn to a method of determining a splicing variant of tumor necrosis factor receptor protein in a sample using an antibody.

Applicants strongly traverse the Examiner's restriction requirement. In a conventional restriction requirement, regardless of the election made, the Examiner will examine a reasonable number of sequences that fall within a generic claim. However, in the present instance the Examiner has restricted sequences within the generic claim. For instance, claim 1 embodies 8 possible sequences (SEQ ID NOS 1-8), however, the Examiner has created separate groups for each sequence, thus requiring Applicants to select a single sequence for prosecution on the merits. This is an improper restriction requirement and should be withdrawn.

The Examiner fails to provide any specific reason why each of the inventive sequences should be restricted. The Examiner has simply asserted that each of these sequences possesses differences in structure and function and are therefore distinct from each other. However, Applicants submit that this generic statement is unsupported by the present facts and insufficient to shift the burden to the Applicant. The Examiner has provided absolutely no evidence to explain why these sequences are distinct. In fact, the present specification clearly identifies SEQ ID NOS 1-8 as novel isolated nucleic acid molecules which represent splicing variants of the tumor necrosis factor receptor. Thus, the Examiner's statement that they possess characteristics which differ in function is not supported by the present specification.

Regardless of the present facts, to aid the biotechnology industry in protecting its intellectual property, the Commissioner has partially waived the requirements of 37 C.F.R. §1.141 et seq. to permit a "reasonable number" of nucleotide sequences to be claimed in a single application. *See Examination of Patent Applications Containing Nucleotide Sequences*, 1192 OG 68 (November 19, 1996). MPEP §803.04 explains that normally 10 sequences constitute a "reasonable number" of sequences

for examination purposes. Thus, 10 independent and distinct nucleotide sequences should be examined in a single application without restriction. Exceptional cases which are outside of this practice include amino acid sequences reciting 3-dimensional folding. However, the present case is not one of these exceptional cases. Therefore, the Examiner's restriction requirement is completely groundless and should be withdrawn. At the very least, Groups I-VIII should be rejoined.

In order to be fully responsive Applicants hereby elect the amino acid sequence according to SEQ ID NO 9. This is an election with traverse.

Applicants further point out that in the event that allowable subject matter is found for any claim directed to a nucleic or amino acid sequence, claims directed to methods of making or use of these sequences should be rejoined and be found allowable so long as these method claims include all the limitations of the allowable product claim.

The Examiner has also stated that claims 12-15 are improper Markush claims because the multiple elements recited therein are polypeptides, antibodies and nucleic acids, which allegedly do not share common technical features. Applicants respectfully submit that the Examiner

is incorrect in this aspect. Review of the present specification reveals that each of the members of the Markush group are in fact "active ingredients" in a pharmaceutical composition. Thus, the fact that they are not all polypeptides, or all antibodies or all nucleic acids is irrelevant. Reconsideration is requested.

Favorable action on the merits is respectfully solicited.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No. 42,874 at the offices of Birch, Stewart, Kolasch and Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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